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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,261	05/29/2001	Gerald V. Quinnan JR.	044508-5001	2761

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EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,261

Applicant(s)

QUINNAN ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 82 and 83 is/are allowed.
- 6) ☒ Claim(s) 65-72 and 75-94 is/are rejected.
- 7) ☒ Claim(s) 73 and 74 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

In the paper submitted 12/28/04, applicant cancelled all previously pending claims and added new claims 65-94, which are under consideration.

Specification

In response to the objection to the specification, applicant states that a deposit of the original cDNA used to determine the sequence of SEQ ID NO: 1 is in the process of being submitted in accordance with 37 CFR 1.801. Applicant also states that following the deposit, applicant will provide a statement under 37 CFR 1.804. Until the deposit has been perfected, the objection is maintained for reasons of record. Applicant is also required to cancel the new matter presented in the previous amendment presented for Table 3 on page 33.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65-68, 70-72 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite that a sequence is "at least about" a certain percentage. The range this is describing is unclear since 90% sequence identity is "about" 92%, but is not "at least".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 69, 77, 80, 84-89 and 94 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the sequence alignment of the V3 region of SEQ ID NO: 1 to Geneseq database accession no: AAR20883, submitted June 1, 1992 in EP471407-A of Lewis et al.

Claim 69 is drawn to an isolated HIV envelop protein capable of inducing the production of cross-neutralizing anti-serum against multiple strains of HIV *in vitro* that comprises 85% sequence identity to the V3 region of SEQ ID NO: 1. The V3 region of SEQ ID NO: 1 corresponds to residues 301-336 of SEQ ID NO: 1, see line 29 on page 6 of the disclosure. Claim 77 requires that the protein is recombinantly produced and claim 80 states that the protein is linked to another by a peptide linker. Claims 84-89 and 94 are drawn to the instant protein in a pharmaceutical composition with an adjuvant where the composition is suitable for use in humans to generate antibodies. (It is reiterated from the prosecution history of this case that claims drawn to a pharmaceutical composition exclude "vaccines" to treat and prevent HIV, see pages 5-7 of the final rejection of 3/11/3 and applicant's response to the rejection on 11/12/3 on page 8, second paragraph.)

Lewis et al. clearly anticipate the structural features required to induce cross-reactive neutralizing antibodies *in vitro*, see the sequence alignment provided. Lewis et al. also anticipate the HIV envelop protein linked to another protein for the administration to humans with an adjuvant to generate antibodies, see the sequence alignment provided as well as claims 1, 3, 4, 7, 9, 10, 13, 15 and 16. Therefore, Lewis et al. clearly anticipate claims 69, 77, 80, 84-89 and 94.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al.

supra.

The claim requires that the protein is linked by a peptide linker. Although Lewis et al. do not teach peptide linkers to join the two proteins, this would be an obvious alternative to the various linkages taught by Lewis et al. to one of ordinary skill in the art at the time the invention was made.

Claims 75 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. as applied to claims 69, 77, 80, 84-89 and 94 above, and further in view of Cotropia (US 549,060)

Claim 75 is drawn to the instant protein comprising 85% sequence identity to the V3 region of SEQ ID NO: 1 that is cyclic.

See the teachings of Lewis et al. above. The reference does not teach cyclic peptides. However, Cotropia teaches that cyclic HIV envelope proteins are in antigenic conformations, see column 13, lines 1-5. One of ordinary skill in the art at the time the invention was made would have been motivated to provide the peptide of Lewis et al. in a cyclic formation to maintain an antigenic conformation to present to the immune system. Since these cyclic formations of antigenic epitopes are naturally part of an HIV envelope according to Cotropia, one of ordinary

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skill would have had a reasonable expectation of success for producing cyclic HIV envelope proteins.

Claim 79 states that the instant protein is synthetically produced. Cotropia teaches synthetic envelope proteins, see column 5, lines 17-21 and column 8, line 59- column 9, line 33. One of ordinary skill in the art at the time the invention was made would have been motivated to synthetically produce the peptide of Lewis et al. to eliminate the time consuming task of generating the proteins recombinantly. One of ordinary skill would have had a reasonable expectation of producing the protein of Lewis et al. synthetically because proteins are routinely made by this method, see the teachings of Cotropia for example.

Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. as applied to claims 69, 77, 80, 84-89 and 94 above, and further in view of Gilbert et al. (US 4,943,627).

The claim states that the instant protein is glycosylated. Lewis et al do not teach glycosylated peptides. However, Gilbert et al. states that HIV envelope proteins are naturally glycosylated, see column 2, lines 8-15. One of ordinary skill in the art at the time the invention was made would have been motivated to maintain the glycosylated sites of the peptide of Lewis et al. to ensure that the protein maintains the ability to attach to receptors of immune cells for presentation. One of ordinary skill would have had a reasonable expectation of success for producing glycosylated HIV envelope proteins taught by Lewis et al. because glycosylation are naturally part of an HIV envelope according to Gilbert et al.

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Claims 90-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. as applied to claims 69, 77, 80, 84-89 and 94 above, and further in view of Chang et al. (US 5,854,400).

The claims are drawn to a method of making antibodies, where the antibodies are human, mouse monoclonal or polyclonal.

Lewis et al. do not teach antibodies. However, Chang et al. teach murine monoclonal antibodies, humanized antibodies, and polyclonal antibodies against the HIV env proteins, see the abstract, column 2, line 25 - column 3, line 62. One of ordinary skill in the art at the time the invention was made would have been motivated to generate the antibodies of Chang et al. against the protein of Lewis et al. because the antibodies have high potency and neutralizing activity against a single or multiple epitopes of the HIV envelope protein. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of generating the antibodies of Chang et al. against the protein of Lewis et al. by conventional techniques in the art, see the teachings of Chang et al. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Allowable Subject Matter

Claims 73 and 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 82 and 83 are allowed. The prior art does not teach or suggest SEQ ID NO: 1.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

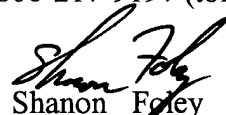
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-Th 6:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley
Primary Examiner
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